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EXAMINER	
TATE, CHRISTOPHER ROBIN	

  

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,713	<b>Applicant(s)</b> DJANG, ARTHUR H.K.	
	<b>Examiner</b> Christopher R. Tate	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>0106</u> . | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

Claims 1-19 are presented for examination on the merits.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8 and 14-19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 5 and 14, and dependent claims 8 and 17, are rendered vague and indefinite by the terms "saponins" and "polyphenols" (recited in claims 5 and 14) and the phrase "N-containing sugars of mulberry" (recited in claims 8 and 17) within the context of defining the claimed compositions as comprising the percentage amount ranges of such saponins, polyphenols, and N-containing sugars therein. That is, it would seem (based upon the teachings of the instant specification including with respect to the preparation of the instantly claimed herbal composition) that the percentage amount ranges recited by these claims are actually reflective of the amount of overall extract for each of the recited herbals, and not of the amount of subset components (saponins, polyphenols, N-containing sugars) therein (e.g., *Gynostemma pentaphyllum* saponins, green tea polyphenols, hawthorn polyphenols, N-containing sugars of mulberry). For example, it is unclear and confusing as to how the instantly claimed composition can comprise the same percentage amount range of each herbal extract as the percentage amount range of the subset components therein: as a comparison - see, e.g., the amount ranges of extracts recited in independent claims 1 and 9 to the amount ranges of saponins/polyphenols recited in

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independent claims 5 and 14, as well as the amount range of mulberry extract recited in claims 2 and 10 to the amount range of N-containing sugars of mulberry recited in claims 8 and 17 (i.e., the naturally-occurring saponins, polyphenols, and/or N-containing sugars present within such extracts). To hasten prosecution, it is suggested that claims 5-8 and 14-18 be cancelled.

Claim 19 recites the limitation "the desired proportions" in line 3 of step (k). There is insufficient antecedent basis for this limitation in the claim. It is suggested that the term "the" be removed from this phrase to overcome this rejection.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Jang (US 5,910,308), in view of Brindavanam et al. (US 2002/0025349), and further in view of Shimizu et al. (JP 2001-213796 - full computer-assisted translation enclosed).

A composition comprising approximate percentage amount ranges of *Gynostemma pentaphyllum* extract and/or saponins, *Camellia sinensis* (green tea) extract and/or polyphenols, *Crataegus pinnatifidia* (hawthorn) extract and/or polyphenols, and *Momordica charantia* (bitter melon) extract, and (optionally) *Morus* (mulberry) extract and/or N-containing sugars, as well as a method of making such an herbal composition.

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D'Jang beneficially teaches a therapeutic herbal composition (including in the pharmaceutical forms instantly claimed) comprising approximate percentage amounts ranges (encompassed by the ranges instantly claimed - including with respect to comprising "about" the ranges instantly claimed) of *Gynostemma pentaphyllum* extract and/or saponins, *Camellia sinensis* (green tea) extract and/or polyphenols, and *Crataegus pinnatifidia* (hawthorn) extract and/or polyphenols (please note that anthocyanins and proanthocyanidins, as well as flavonoids, obtained from this herbal - as taught by D'Jang - are well known in the art to read upon polyphenols), as active ingredients therein, whereby the therapeutic uses include helping to prevent hyperglycemia and/or aiding in reducing the onset of diabetes. D'Jang further beneficially teaches preparing such an herbal composition via the same essential steps as instantly claimed. Please also note that the *Gynostemma pentaphyllum* extract, *Camellia sinensis* (green tea) extract, and *Crataegus pinnatifidia* extract taught by D'Jang would inherently comprise the approximate amount ranges of saponins and/or polyphenols (as recited by some of the instant claims) therein (since they are naturally-occurring components within such herbals) especially given that they are prepared in the same essential manner as instantly disclosed (see entire document including abstract; col 1, line 12 - col 2, line 30; col 3, line 30 - col 4, line 36; cols 5-7, Example 1; and claims). D'Jang does not expressly teach the inclusion of *Momordica charantia* (bitter melon) extract or *Morus* (mulberry) extract therein.

Brindavanam et al. beneficially teaches an anti-diabetic composition comprising *Momordica charantia* (also known as karela) extract as an active ingredient therein, and further disclose that *Momordica charantia* extracts (such as aqueous extracts) are well known in the art to effectively act as anti-diabetic agents including in terms of providing hypoglycemic effects

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such as by lowering the glycemic response without affecting the insulin response and/or increasing glucose tolerance (see entire document including abstract and paragraph [0016]).

Shimizu et al. beneficially teach an anti-diabetic composition comprising a mulberry (*Morus*) leaf extract (e.g., a water extract thereof) as an active ingredient therein, and further disclose that mulberry leaf extract is well known in the art to effectively act as anti-diabetic agents based upon its recognized hypoglycemic activity (see entire computer-assisted English translation including abstract and paragraphs [0006] & [0020] thereof).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit - based upon the beneficial teachings provided by the cited references above, since each is well known in the art for the same purpose (i.e., as effective anti-diabetic agents) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. In re Kerkhoven, 626 F.2d 846, 850, 205 U.S.P.Q. 1069 (CCPA 1980), In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The adjustment of particular conventional working conditions (e.g., determining an appropriate approximate amount range for one or more of such herbal extracts therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher R. Tate  
Primary Examiner  
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